## CLAIMS

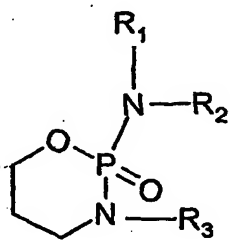
1. A process for preparation of a low toxicity, stable oxazaphosphorine-containing composition comprising an oxazaphosphorine antineoplastic, mesna and an etherified β-cyclodextrin; the process comprising the steps of:

   i) adding the oxazaphosphorine antineoplastic to an aqueous solution of an etherified β-cyclodextrin;

   ii) adding mesna as such or as an aqueous solution optionally containing an etherified β-cyclodextrin to the oxazaphosphorine solution of step (i); and

   iii) mixing the resultant aqueous solution and, optionally, making up the volume with water.

2. A process as claimed in Claim 1, wherein the oxazaphosphorine antineoplastic is of the formula:



in which at least two of $R_1$, $R_2$ and $R_3$ independently are 2-chloroethyl and the remaining R radical is hydrogen.

3. A process as claimed in Claim 2, wherein the oxazaphosphorine antineoplastic is Cyclophosphamide ($R_1$ = $R_2$ = chloroethyl & $R_3$ = hydrogen).

4. A process as claimed in Claim 2, wherein the oxazaphosphorine antineoplastic is Ifosfamide ($R_1$ = $R_3$ = chloroethyl & $R_2$ = hydrogen).

5. A process as claimed in any one of the preceding claims, wherein the etherified β-cyclodextrin used is Hydroxypropyl Beta Cyclodextrin (HPBCD).

6. A process as claimed in Claim 5, wherein the molar substitution of HPBCD is from about 0.5 to about 1.2.

7. A process as claimed in any one of the preceding claims, wherein the oxazaphosphorine antineoplastic content of the composition is from about 1 mg/ml to about 1000 mg/ml.

8. A process as claimed in Claim 7, wherein said oxazaphosphorine antineoplastic content is from about 25 mg/ml to about 750 mg/ml.

9. A process as claimed in Claim 8, wherein said oxazaphosphorine antineoplastic content is from about 50 mg/ml to about 500 mg/ml.

10. A process as claimed in Claim 9, wherein said oxazaphosphorine antineoplastic content is about 50 mg/ml.

11. A process as claimed in Claim 9, wherein said oxazaphosphorine antineoplastic content is about 500 mg/ml.

12. A process as claimed in any one of the preceding claims, wherein the ratio of oxazaphosphorine antineoplastic to mesna is in the range of about 20 : 1 to about 1 : 2 on a weight basis.

13. A process as claimed in claim 12, wherein the ratio of oxazaphosphorine antineoplastic to mesna is in the range of about 10 : 1 to about 1 : 1 on a weight basis.

14. A process as claimed in claim 13, wherein the ratio of oxazaphosphorine antineoplastic to mesna is 10 : 2 on a weight basis.

15. A process as claimed in claim 13, wherein the ratio of oxazaphosphorine antineoplastic to mesna is 10 : 6 on a weight basis.

16. A process as claimed in any one of the preceding claims, wherein the content of etherified β-cyclodextrin in the composition is about 1% to about 60% w/v.

17. A process as claimed in Claim 16, wherein said etherified β-cyclodextrin content is about 2.5% to about 40% w/v.

18. A process as claimed in Claim 17, wherein said etherified β-cyclodextrin content is about 5% to about 20% w/v.

19. A process as claimed in any one of the preceding claims, wherein one or more conventional parenteral additives are incorporated into the aqueous solution of Claim 1 step (i) or Claim 1 step (ii) or in water used for making up the volume in Claim 1 step (iii).

20. A process as claimed in any one of the preceding claims, wherein said mixture of resultant aqueous solutions is sterilized by filtering through a sterilising grade filter.

21. A process as claimed in Claim 20, wherein the filtrate from the sterilising grade filter is aseptically filled into sterile containers and the filled containers are sealed.

22. A process as claimed in Claim 1 and substantially as herein before described with reference to any of the Examples.

23. A stable oxazaphosphorine-containing composition obtainable by a process as claimed in any one of the preceding claims.

24. A stable oxazaphosphorine-containing composition prepared by a process as claimed in any one of the preceding claims.

25. The use of a stable oxazaphosphorine-containing composition as defined in Claim 23 or Claim 24 in the manufacture of a medicament for the treatment of malignant disease.

26. A method of treating a malignant disease comprising administering to a patient suffering said disease an effective amount of a sterile stable oxazaphosphorine-containing composition as defined in Claim 23 or Claim 24.